IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., *Plaintiff*, v. PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC., *Defendants*.	Civil Action No.: 13-cv-1524-SLR

PLAINTIFF'S REPLY TO DEFENDANTS PAR PHARMACEUTICAL, INC. AND PAR PHARMACEUTICAL COMPANIES, INC.'S COUNTERCLAIMS

Plaintiff/Counterclaim-Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") hereby replies to the counterclaims asserted by Defendants/Counterclaim-Plaintiffs Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par" or "Defendants") as follows:

COUNTERCLAIMS

Counterclaimants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par"), assert the following counterclaims against Plaintiff/Counterdefendants Takeda Pharmaceuticals, U.S.A., for declaratory judgment that the sale and/or offer for sale of the 0.6 mg colchicine tablets described in Par's ANDA No. 203976 ("Par's ANDA Product") will not contribute to the infringement of U.S. Patent Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,093,297 ("the '297 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively, "the Gout Patents"); will not infringe U.S. Patent Nos. 7,906,519 ("the '519 patent"); 7,935,731 ("the '731 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); and 8,097,298 ("the '298 patent") (collectively, the "FMF Patents"); and/or that the Gout Patents and FMF Patents are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

THE PARTIES

1. Counterclaimant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

ANSWER: On information and belief, Takeda admits the allegations in this paragraph.

2. Counterclaimant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

ANSWER: On information and belief, Takeda admits the allegations in this paragraph.

3. On information and belief, and based on its allegations, Counterclaim-Defendant/Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: Admitted.

NATURE OF THE ACTION

4. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief—a declaration that the sale, offer-for-sale, distribution, or importation into the United States of the 0.6 mg colchicine tablets described in Par Pharmaceutical, Inc.'s Abbreviated New Drug Application ("ANDA") No. 203976 ("Par's ANDA Product") will not contribute to the infringement of the Gout Patents, and/or that the Gout Patents are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that Par's counterclaims purport to arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*,

and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Takeda denies all remaining allegations in this paragraph. Further, Takeda denies that Par is entitled to any of the requested relief and denies that any claim of the patents in suit is invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Par and Takeda, arising under the patent laws of the United States, 35 U.S.C. §1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

6. This Court has personal jurisdiction over Takeda based on, inter alia, its filing of this lawsuit in this jurisdiction.

ANSWER: Takeda admits that this Court has personal jurisdiction over it for purposes of this action only.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

ANSWER: Takeda admits that venue is proper for purposes of this action only.

BACKGROUND

8. The '004 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as November 17, 2009.

ANSWER: Admitted.

9. The ’758 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares” and states its date of issue as October 13, 2009.

ANSWER: Admitted.

10. The ’681 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as October 26, 2010.

ANSWER: Admitted.

11. The ’269 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as March 29, 2011.

ANSWER: Admitted.

12. The ’647 patent, on its face, is titled “Colchicine Compositions and Methods” and states its date of issue as June 21, 2011.

ANSWER: Admitted.

13. The ’648 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as June 21, 2011.

ANSWER: Admitted.

14. The ’938 patent, on its face, is titled “Colchicine Compositions and Methods” and states its date of issue as July 19, 2011.

ANSWER: Admitted.

15. The ’296 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics” and states its date of issue as January 10, 2012.

ANSWER: Admitted.

16. The ’297 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as January 10, 2012.

ANSWER: Admitted.

17. The ’655 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics” and states its date of issue as January 17, 2012.

ANSWER: Admitted.

18. The ’395 patent, on its face, is titled “Colchicine Compositions and Methods” and states its date of issue as April 9, 2013.

ANSWER: Admitted.

19. The ’396 patent, on its face, is titled “Colchicine Compositions and Methods” and states its date of issue as April 9, 2013.

ANSWER: Admitted.

20. The ’721 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as May 14, 2013.

ANSWER: Admitted.

21. The ’722 patent, on its face, is titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent” and states its date of issue as May 14, 2013.

ANSWER: Admitted.

22. The earliest effective filing date to which the ’758, ’655, ’004, ’296, ’731, and ’298 patents claim priority on their faces is October 15, 2008.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that the ’758, ’655, ’004, ’296, ’731, and ’298 patents facially list a priority date of October 15, 2008. Takeda denies any remaining allegations in this paragraph.

23. The earliest effective filing date to which the ’681, ’648, ’269, ’297, ’721, and ’722 patents claim priority on their faces is January 14, 2009.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that the ’681, ’648,

'269, '297, '721, and '722 patents facially list a priority date of January 14, 2009. Takeda denies any remaining allegations in this paragraph.

24. The earliest effective filing date to which the '647, '938, '395, and '396 patents claim priority on their faces is October 5, 2007.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that the '647, '938, '395, and '396 patents facially list a priority date of October 5, 2007. Takeda denies any remaining allegations in this paragraph.

25. On information and belief, and based on Takeda's allegations, Takeda is the owner of all right, title, and interest in the Gout Patents.

ANSWER: Admitted.

26. On information and belief, and based on Takeda's allegations, Takeda is the holder of New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353 for colchicine, sold in the United States as COLCRYS®.

ANSWER: Admitted.

27. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 22-351 on July 30, 2009.

ANSWER: Admitted.

28. On information and belief, the FDA approved NDA No. 22-352 on July 29, 2009.

ANSWER: Admitted.

29. On information and belief, the FDA approved NDA No. 22-353 on October 16, 2009.

ANSWER: Admitted.

PAR'S ANDA PRODUCT

30. On September 4, 2014, Takeda served Par with an Amended Complaint alleging that Par will contribute to the infringement of the Gout Patents by selling, offering for sale, distributing, or importing Par's ANDA Product upon approval of ANDA No. 20-3976.

ANSWER: Admitted.

31. On July 19, 2013, Par submitted a label amendment to the FDA such that the proposed label originally submitted with ANDA No. 20-3976 would be amended for the purpose of limiting FDA approval of its ANDA Product to the treatment of FMF, and that pursuant to 21 U.S.C. §355(j)(2)(A)(viii), Par sought to carve out from the FDA-approved COLCRYS® label information regarding the treatment and prevention of gout flares, including all dosing instructions for the treatment and prevention of gout flares.

ANSWER: On information and belief, Takeda admits that Par submitted a gratuitous label amendment to the FDA regarding ANDA No. 20-3976. Takeda denies any remaining allegations in this paragraph.

32. Based upon the label amendment to the FDA described in Paragraph 30, the proposed labeling for Par's ANDA Product will not include any dosage or administration instructions directing a patient to use its product to treat or prevent gout flares, nor any instructions for dose modification in the event of concomitant therapy of gout with another substance.

ANSWER: Takeda denies the allegations as stated in this paragraph. To the extent the paragraph refers to the label amendment to the FDA described in Paragraph 31, Takeda admits that Par submitted a gratuitous label amendment to the FDA regarding ANDA No. 20-3976 by which Par purportedly intended to remove explicit dosage or administration instructions relating to treating or preventing gout flares, and by which Par purportedly intended to remove explicit instructions for dose modification for concomitant administration of Par's ANDA Product with another substance.

33. Based upon the label amendment to the FDA described in Paragraph 30, the proposed labeling for Par's ANDA Product will include dosage and administration instructions directing a patient to use Par's ANDA Product for treatment of FMF.

ANSWER: Takeda denies the allegations in this paragraph. To the extent the paragraph refers to the label amendment to the FDA described in Paragraph 31, Takeda admits that Par submitted a gratuitous label amendment to the FDA regarding ANDA No. 20-3976 by which Par purportedly intended to include dosage and administration instructions directing a patient to use Par's ANDA Product for treatment of FMF.

TAKEDA'S FDA APPROVED PRODUCT LABEL FOR COLCRYS®

34. Upon information and belief, a true and correct copy of Takeda's most recent FDA-approved product label for COLCRYS® is attached to these Counterclaims as Exhibit 1.

ANSWER: Admitted.

35. The "INDICATIONS AND USAGE" section of Takeda's FDA approved product label for COLCRYS® lists that "COLCRYS is indicated for prophylaxis of gout flares." COLCRYS® Prescribing Information, Exhibit 1, at 3.

ANSWER: Admitted.

36. The "INDICATIONS AND USAGE" section of Takeda's FDA approved product label for COLCRYS® also lists that "COLCRYS tablets are indicated for treatment of acute gout flares when taken at the first sign of flare." *Id.*

ANSWER: Admitted.

37. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® also states that the "recommended dose of COLCRYS for treatment of a gout flare is 1.2 mg (2 tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later." *Id.*

ANSWER: Admitted.

38. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® states that the "recommended dosage of COLCRYS for prophylaxis of gout flares for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose for prophylaxis of gout flares is 1.2 mg/day." *Id.*

ANSWER: Admitted.

39. The "DOSAGE AND ADMINISTRATION" section also states that

> Co-administration of COLCRYS with drugs known to inhibit CYP3A4 and/or P-glycoprotein (P-gp) increases the risk of colchicine-induced toxic effects (Table 1). If patients are taking or have recently completed treatment with drugs listed in Table 1 within the prior 14 days, the dose adjustments are as shown on the table below. . .

Table 1. COLCRYS Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡ (pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

P-gp Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Cyclosporine Ranolazine	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other P-gp inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

*For magnitude of effect on colchicine plasma concentrations *[see Pharmacokinetics (12.3)]*

†Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with strong CYP3A4 or P-gp inhibitors *[see Contraindications (4)]*

‡When used in combination with Ritonavir, see dosing recommendations for strong CYP3A4 inhibitors *[see Contraindications (4)]*

Table 1. COLCRYS Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡ (pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

P-gp Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Cyclosporine Ranolazine	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other P-gp inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

*For magnitude of effect on colchicine plasma concentrations *[see Pharmacokinetics (12.3)]*

†Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with strong CYP3A4 or P-gp inhibitors *[see Contraindications (4)]*

‡When used in combination with Ritonavir, see dosing recommendations for strong CYP3A4 inhibitors *[see Contraindications (4)]*

Id at 4-5 (internal cross-references omitted).

ANSWER: Admitted.

40. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® thus instructs doctors to administer or patients to take 0.6 mg of colchicine once or twice a day (i.e., up to 1.2 mg of colchicine a day in the form of two 0.6 mg colchicine tablets) for prophylaxis of gout flares if the patient is not taking or has not recently completed treatment with CYP3A4 inhibitors such as ketoconazole, clarithromycin, ritonavir, erythromycin, or verapamil. *Id.*

ANSWER: Admitted.

41. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® instructs doctors to administer or patients to take 1.2 mg (2 tablets) of colchicine at the first sign of the gout flare followed by 0.6 mg (1 tablet) of colchicine one hour later for treatment of gout flares only if the patient is not taking or has not recently completed treatment with CYP3A4 inhibitors such as ketoconazole, clarithromycin, ritonavir, erythromycin, or verapamil. *Id.*

ANSWER: Admitted.

42. The "CLINICAL STUDIES" section of Takeda's FDA approved product label for COLCRYS® states that

> The evidence for the efficacy of colchicine in patients with chronic gout is derived from the published literature. Two randomized clinical trials assessed the efficacy of colchicine 0.6 mg twice a day for the prophylaxis of gout flares in patients with gout initiating treatment with urate lowering therapy. In both trials, treatment with colchicine decreased the frequency of gout flares.

Id. at 19.

ANSWER: Admitted.

43. Upon information and belief, the "evidence for the efficacy of colchicine in patients with chronic gout" referenced in Takeda's FDA approved product label for COLCRYS® includes at least two pieces of published literature: "Prophylactic Colchicine Therapy of Intercritical Gout: A Placebo-Controlled Study in Probenecid-Treated Patients" by Paulus, et al. (Arthritis & Rheumatism, 17:5, 609, 1974) ("The Paulus Study") and "Colchicine for Prophylaxis of Acute Flares when Initiating Allopurinol for Chronic Gouty Arthritis" by Borstad, Bryant et al. (J. Rheum. 31:12, 2429, 2004) ("The Borstad Study"). *See* Exhibit 2,

United States Food and Drug Administration Summary Review Letter for NDA 22-353 (Colcrys (colchicine)) at 10-13 (Oct. 16, 2009).

ANSWER: Takeda admits that the Paulus Study and Borstad Study are referenced in correspondences with the FDA regarding NDA No. 220353. Takeda denies any remaining allegations in this paragraph.

44. The Paulus Study was published in 1974, more than one year prior to October 5, 2007.

ANSWER: Admitted.

45. The Borstad Study was published in 2004, more than one year prior to October 5, 2007.

ANSWER: Admitted.

46. Upon information and belief, Takeda advertises that COLCRYS "helps prevent gout flares[.]" *See* Exhibit 3, "About COLCRYS (colchicine, USP)" (available at www.colcrys.com/about.aspx; last accessed September 12, 2014).

ANSWER: Admitted.

47. Upon information and belief, Takeda advertises that "based on current treatment guidelines from the American College of Rheumatology, your doctor may prescribe COLCRYS (colchicine, USP) along with uric acid-lowering medicine. For preventing flares, when uric acid-lowering medication is taken along with COLCRYS, 1 or 2 tablets (up to 1.2 mg daily) is recommended daily." *See* Exhibit 4, "Taking COLCRYS (colchicine, USP) Medication for Gout" (available at www.colcrys.com/taking-colcrys.aspx; last accessed September 12, 2014).

ANSWER: Admitted.

48. Upon information and belief, administering 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares is a substantial use of 0.6 mg colchicine tablets.

ANSWER: Takeda admits that administering 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares is one type of use of 0.6 mg

colchicine tablets. Except as expressly admitted, Takeda denies any remaining allegations in this paragraph.

49. Upon information and belief, administering 0.6 mg a day of colchicine in the form of one 0.6 mg colchicine tablet for the prophylaxis of gout flares is a substantial use of 0.6 mg colchicine tablets.

ANSWER: Takeda admits that administering 1.2 mg a day of colchicine in the form of one 0.6 mg colchicine tablets for the prophylaxis of gout flares is one type of use of 0.6 mg colchicine tablets. Except as expressly admitted, Takeda denies any remaining allegations in this paragraph.

COUNTERCLAIM COUNT I
(Non-Infringement of the'758 Patent)

50. Par incorporates by reference Paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 49 of its Reply to Par's Counterclaims.

51. The '758 patent has eleven claims in total.

ANSWER: Admitted.

52. Claims 1 and 10 of the '758 are the only independent claims of the '758 patent.

ANSWER: Admitted.

53. Claims 2-9 of the '758 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

54. Claim 11 of the '758 patent depends from claim 10.

ANSWER: Admitted.

55. Claim 1 of the ’758 patent recites the following:

> 1. A method of using colchicine to treat a gout flare in a human patient who is receiving concomitant administration of clarithromycin or erythromycin, said method comprising:
>
> determining a first colchicine dosage amount adapted for oral administration to the patient to treat a gout flare in the absence of concomitant administration of clarithromycin or erythromycin,
>
> determining a second colchicine dosage amount that is about a two thirds reduction of the first colchicine dosage amount,
>
> orally administering the second colchicine dosage amount to the patient who is experiencing a gout flare and is concomitantly receiving administration of clarithromycin or erythromycin,
>
> wherein concomitant administration of clarithromycin or erythromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount, and not repeating colchicine administration for at least three days.

ANSWER: Admitted.

56. Claim 10 of the ’758 patent recites the following:

> 10. A method of using colchicine to treat a gout flare in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin or erythromycin, said method comprising:
>
> administering a reduced colchicine dosage amount to the patient to treat gout flares, wherein the reduced colchicine dosage amount is about 50% to about 75% of a manufacturer’s recommended colchicine dosage amount in the absence of concomitant clarithromycin or erythromycin administration, and
>
> not repeating colchicine administration for at least three days,
>
> wherein concomitant administration of clarithromycin or erythromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

ANSWER: Admitted

57. Physicians can and will prescribe Par's ANDA Product without concomitant administration of clarithromycin or erythromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with clarithromycin or erythromycin. Takeda denies any remaining allegations in this paragraph.

58. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin or erythromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA Product to a patient whois not otherwise also being treated with clarithromycin or erythromycin. Takeda denies any remaining allegations in this paragraph.

59. Par will not contribute to the infringement of any claim of the '758 patent.

ANSWER: Denied.

60. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '758 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

61. Par is entitled to a judicial declaration that Par's ANDA Product will not contribute to the infringement of the '758 patent.

ANSWER: Denied.

COUNTERCLAIM COUNT II
(Non-Infringement of the '004 Patent)

62. Par incorporates by reference Paragraphs 1 through 61 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 61 of its Reply to Par's Counterclaims.

63. The '004 patent has eight claims in total.

ANSWER: Admitted.

64. Claims 1 and 5 of the '004 are the only independent claims of the '004 patent.

ANSWER: Admitted.

65. Claims 2-4 and 8 of the '004 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

66. Claims 6 and 7 of the '004 patent depend from claim 10.

ANSWER: Admitted.

67. Claim 1 of the '004 patent recites the following:

> 1. A method of using colchicine for prophylactic treatment of gout flares in a human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> orally administering a second colchicine daily dosage amount for prophylactic treatment of gout flares to the human gout patient who is concomitantly receiving administration of clarithromycin, wherein the second colchicine daily dosage amount is a 75% reduction of a first colchicine daily dosage amount suitable for daily oral administration for the prophylactic treatment of gout

> flares in the absence of concomitant administration of clarithromycin, wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount, and
>
> wherein the first colchicine daily dosage amount is 1.2 mg administered as two 0.6 mg doses per day, and the second colchicine daily dosage amount is 0.3 mg per day, or wherein the first colchicine daily dosage amount is 0.6 mg per day and the second colchicine daily dosage amount is 0.15 mg per day administered as 0.3 mg every other day, or wherein the first colchicine daily dosage amount is 0.6 mg per day and the second colchicine daily dosage amount is 0.15 mg per day.

ANSWER: Admitted.

68. Claim 5 of the '004 patent recites the following:

> 5. A method of using colchicine for prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> administering a reduced colchicine daily dosage amount to the patient for prophylactic treatment of gout flares, wherein the reduced colchicine daily dosage amount is 75% of a manufacturers' recommended colchicine daily dosage amount for the prophylactic treatment of gout flares in the absence of concomitant clarithromycin administration, wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

ANSWER: Admitted.

69. Physicians can and will prescribe Par's ANDA Product without concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

70. Claim 1 of the ’004 patent sets forth a substantial use that will not infringe the ’004 patent, in that it describes “a first colchicine daily dosage amount suitable for daily oral administration for the prophylactic treatment of gout flares in the absence of concomitant administration of clarithromycin” which is “1.2 mg administered as two 0.6 mg doses per day[.]”

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

71. Physicians can and will prescribe, *inter alia*, Par’s ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par’s ANDA product to a patient who is not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

72. Par will not contribute to the infringement of any claim of the ’004 patent.

ANSWER: Denied.

73. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par’s ANDA Product of the ’004 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph

74. A judicial declaration that Par’s ANDA Product will not contribute to the infringement of the ’004 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT III
(Non-Infringement of the '681 Patent)

75. Par incorporates by reference Paragraphs 1 through 74 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 74 of its Reply to Par's Counterclaims.

76. The '681 patent has four claims in total.

ANSWER: Admitted.

77. Claim 1 of the '681 patent is the only independent claim of the '681 patent.

ANSWER: Admitted.

78. Claims 2-4 of the '681 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

79. Claim 1 of the '681 patent recites the following:

> 1. A method of treating a patient in need of treatment for the prophylaxis of gout flares with colchicine, comprising orally administering to the patient in need of treatment for the prophylaxis of gout flares, an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of 200 mg per day of ritonavir;
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of 0.6 mg twice per day or 0.6 mg once per day, which is an amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

ANSWER: Admitted.

80. If, as Takeda has alleged, physicians will prescribe Par's ANDA Product for gout consistent with their previous prescription practices for COLCRYS®, physicians can and will prescribe Par's ANDA Product without concomitant administration of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

81. Claim 1 of the '681 patent sets forth a substantial non-infringing use, in that it describes administering 0.6 mg twice per day or 0.6 mg once per day as an amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

82. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that it a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

83. Par will not contribute to the infringement of any claim of the '681 patent.

ANSWER: Denied.

84. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '681 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

85. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '681 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT IV
(Non-Infringement of the '269 Patent)

86. Par incorporates by reference Paragraphs 1 through 85 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 85 of its Reply to Par's Counterclaims.

87. The '269 patent has one claim.

ANSWER: Admitted.

88. Claim 1 of the '269 patent recites the following:

> 1. A method of treating a patient in need of treatment for gout flares with colchicine, comprising
>
> orally administering to the patient in need of treatment for gout flares, an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of 200 mg per day of ritonavir,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of an intended daily dosage amount in the absence of concomitant ritonavir, wherein the intended daily dosage amount in the absence of concomitant ritonavir is 1.2 mg at the first sign of

flare, followed by 0.6 mg one hour later, dose to be repeated no earlier than 3 days.

ANSWER: Admitted.

89. Physicians can and will prescribe Par's ANDA Product without concomitant administration of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

90. Claim 1 of the '269 patent sets forth a substantial non-infringing use, in that it describes an intended daily dosage amount of colchicine in the absence of concomitant ritonavir which is 1.2 mg colchicine at the first sign of flare, followed by 0.6 mg colchicine one hour later, dose to be repeated no earlier than 3 days.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

91. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

92. Par will not contribute to the infringement of any claim of the '269 patent.

ANSWER: Denied.

93. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '269 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

94. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '269 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT V
(Non-Infringement of the '647 Patent)

95. Par incorporates by reference Paragraphs 1 through 94 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 94 of its Reply to Par's Counterclaims.

96. The '647 patent has one claim.

ANSWER: Admitted.

97. Claim 1 of the '647 patent recites the following:

> 1. A method of treating a patient having an acute gouty arthritis attack with colchicine consisting of
>
> administering 1.2 mg oral colchicine to a human patient having an acute gouty arthritis attack at the onset of the acute gouty arthritis attack, followed by 0.6 mg oral colchicine one hour later.

ANSWER: Admitted.

98. Par's ANDA Product is not especially adapted for infringement of the '647 patent because Par's ANDA Product may be taken for, inter alia, FMF and prophylaxis of gout flares.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

99. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient in need thereof.

ANSWER: Admitted.

100. Par will not contribute to the infringement of any claim of the '647 patent.

ANSWER: Denied.

101. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '647 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

102. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '647 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT VI
(Non-Infringement of the '648 Patent)

103. Par incorporates by reference Paragraphs 1 through 102 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 102 of its Reply to Par's Counterclaims.

104. The '648 patent has eight claims.

ANSWER: Admitted.

105. Claim 1 of the '648 patent is the only independent claim in the '648 patent.

ANSWER: Admitted.

106. Claims 2-8 of the '648 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

107. Claim 1 of the '648 patent recites the following:

> 1. A method of treating a patient with colchicine, comprising
>
> orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of ketoconazole,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of an intended daily dosage amount of colchicine,
>
> and wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant ketoconazole.

ANSWER: Admitted.

108. Physicians can and will prescribe Par's ANDA Product without concomitant administration of ketoconazole.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ketoconazole. Takeda denies any remaining allegations in this paragraph.

109. If, as Takeda has alleged, physicians will prescribe Par's ANDA Product for gout consistent with their previous prescription practices for COLCRYS®, physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ketoconazole.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ketoconazole. Takeda denies any remaining allegations in this paragraph.

110. Par will not contribute to the infringement of any claim of the '648 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

111. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '648 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

112. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce

infringement of any valid or enforceable claim of the '648 patent under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

113. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '648 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

114. A judicial declaration that Par's ANDA Product will not infringe the '648 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT VII
(Non-Infringement of the '938 Patent)

115. Par incorporates by reference Paragraphs 1 through 114 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 114 of its Reply to Par's Counterclaims.

116. The '938 patent has only one claim.

ANSWER: Admitted.

117. Claim 1 of the ’938 patent recites the following:

> 1. A method of treating a gout flare with colchicine in a patient undergoing colchicine prophylactic treatment of gout flares, consisting of
>
> Administering to a patient having a gout flare while undergoing prophylactic treatment of gout flares
>
> 1.2 mgA oral colchicine at the onset of the acute gout flare, followed by 0.6 mgA oral colchicine about one hour later; and
>
> After waiting 12 hours, continuing prophylactic treatment consisting of 0.6 mgA or 1.2 mgA oral colchicine daily.

ANSWER: Admitted.

118. Par’s ANDA Product is not especially adapted for infringement of the ’938 patent because Par’s ANDA Product may be taken for, inter alia, FMF and prophylaxis of gout flares.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

119. Claim 1 of the ’938 patent sets forth a substantial non-infringing use, in that it describes prophylactic treatment of gout flares with colchicine consisting of 0.6 mgA or 1.2 mgA oral colchicine daily.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

120. Physicians can and will prescribe Par’s ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient.

ANSWER: Admitted.

121. Par will not contribute to the infringement of any claim of the ’938 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

122. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '938 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

123. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '295 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT VIII
(Non-Infringement of the '296 Patent)

124. Par incorporates by reference Paragraphs 1 through 123 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 123 of its Reply to Par's Counterclaims.

125. The '296 patent has three claims.

ANSWER: Admitted.

126. Claim 1 of the '296 patent is the only independent claim in the '296 patent.

ANSWER: Admitted.

127. Claims 2-3 of the ’296 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

128. Claim 1 of the ’296 patent recites the following:

> 1. A method of using colchicine to treat a gout flare in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> orally administering a reduced colchicine dosage amount to the patient to treat gout flares, wherein the reduced colchicine dosage amount is about a 50% to about a 75% reduction of a colchicine dosage amount adapted for oral administration to the gout patient to treat gout flares in the absence of concomitant administration of clarithromycin, and
>
> not repeating colchicine administration for at least three days,
>
> wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the reduced colchicine dosage amount.

ANSWER: Admitted.

129. Physicians can and will prescribe Par’s ANDA Product without concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par’s ANDA product to a patient who not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

130. Claim 2 of the ’296 patent sets forth a substantial non-infringing use, in that it describes a colchicine dosage amount adapted for oral administration to the gout patient to treat gout flares in the absence of concomitant administration of clarithromycin which is 1.2 mg at the first sign of a flare followed by 0.6 mg one hour later.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

131. Physicians can and will prescribe Par's ANDA Products at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that it a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

132. Par will not contribute to the infringement of any claim of the '296 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

133. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '296 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

134. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '296 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT IX
(Non-Infringement of the '297 Patent)

135. Par incorporates by reference Paragraphs 1 through 134 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 134 of its Reply to Par's Counterclaims.

136. The '297 patent has nine claims.

ANSWER: Admitted.

137. Claim 1 of the '297 patent is the only independent claim in the '297 patent.

ANSWER: Admitted.

138. Claims 2-9 of the '297 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

139. Claim 1 of the '297 patent recites the following:

> 1. A method of treating a patient in need of treatment for gout or familial Mediterranean fever with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of a recommended daily dosage of ritonavir,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of a daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

ANSWER: Admitted.

140. Physicians can and will prescribe Par's ANDA Product without concomitant administration of a recommended daily dosage of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

141. Claim 2 of the '297 patent sets forth a substantial non-infringing use, in that it describes "treating with colchicine... for the prophylaxis of gout flares, and wherein the daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir is 0.6 mg twice daily or 0.6 mg once daily."

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

142. Physicians can and will prescribe Par's ANDA Products at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with ritonavir. Takeda denies any remaining allegations in this paragraph.

143. Par will not contribute to the infringement of any claim of the '297 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

144. The manufacture, use, sale, offer for sale, and/or importation into the States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '297 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

145. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '297 patent under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

146. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '297 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

147. A judicial declaration that Par's ANDA Product will not infringe the '297 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT X
(Non-Infringement of the '655 Patent)

148. Par incorporates by reference Paragraphs 1 through 147 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 147 of its Reply to Par's Counterclaims.

149. The '655 patent has five claims.

ANSWER: Admitted.

150. Claim 1 of the '655 patent is the only independent claim in the '655 patent.

ANSWER: Admitted.

151. Claims 2-5 of the '655 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

152. Claim 1 of the '655 patent recites the following:

> 1. A method of using colchicine for the prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> orally administering a reduced colchicine daily dosage amount to the patient for prophylactic treatment of gout flares, wherein the reduced daily colchicine dosage amount is a 75% reduction of a colchicine dosage amount adapted for oral administration to the gout patient for the prophylaxis of gout flares in the absence of concomitant administration of clarithromycin,
>
> wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

ANSWER: Admitted.

153. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could

prescribe Par's ANDA product to a patient who not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

154. Claim 2 of the '655 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes a -colchicine dosage amount adapted for oral administration to a the gout patient for the prophylaxis of gout flares in the absence of concomitant administration of clarithromycin" which "is 0.6 mg twice per day."

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

155. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with clarithromycin. Takeda denies any remaining allegations in this paragraph.

156. Par will not contribute to the infringement of any claim of the '655 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

157. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '655 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an

actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

158. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '655 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XI
(Non-Infringement of the '395 Patent)

159. Par incorporates by reference Paragraphs 1 through 158 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 158 of its Reply to Par's Counterclaims.

160. The '395 patent has twenty claims.

ANSWER: Admitted.

161. Claims 1 and 13 of the '395 patent are the only independent claims in the '395 patent.

ANSWER: Admitted.

162. Claims 2-12 of the '395 patent depend, either directly or indirectly, from claim 1

ANSWER: Admitted.

163. Claims 14-20 of the '395 patent depend, either directly or indirectly, from claim 13.

ANSWER: Admitted.

164. Claim 1 of the '395 patent recites the following:

> 1. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration;
>
> the method providing lower incidence of an adverse event in a randomized placebo-controlled study compared to a second method of orally administering 4.8 mg oral colchicine over a period of 6 hours.

ANSWER: Admitted.

165. Claim 13 of the ’395 patent recites the following:

> 13. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration;
>
> the method characterized by an incidence of a gastrointestinal adverse event that is not significantly different from incidence of the gastrointestinal adverse event characterizing administration of placebo.

ANSWER: Admitted.

166. Par’s ANDA Product is not especially adapted for infringement of the ’395 patent because Par’s ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

167. Claim 1 of the ’395 patent sets forth a substantial use that will not infringe the ’395 patent, in that it describes “a second method of orally administering 4.8 mg oral colchicine over a period of 6 hours.”

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

168. Physicians can and will prescribe Par’s ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient.

ANSWER: Admitted.

169. Par will not contribute to the infringement of any claim of the ’395 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

170. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par’s ANDA Product of the ’395 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

171. A judicial declaration that Par’s ANDA Product will not contribute to the infringement of the ’395 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XII
(Non-Infringement of the '396 Patent)

172. Par incorporates by reference Paragraphs 1 through 171 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 171 of its Reply to Par's Counterclaims.

173. The '396 patent has twenty-six claims.

ANSWER: Admitted.

174. Claims 1, 6, 11, and 19 of the '396 patent are the only independent claims in the '396 patent.

ANSWER: Admitted.

175. Claims 2-5 of the '396 patent depend, either directly or indirectly, from claim 1

ANSWER: Admitted.

176. Claims 7-10 of the '396 patent depend, either directly or indirectly, from claim 6.

ANSWER: Admitted.

177. Claims 12-18 of the '396 patent depend, either directly or indirectly, from claim

ANSWER: Admitted.

178. Claims 20-26 of the '396 patent depend, either directly or indirectly, from claim 19.

ANSWER: Admitted.

179. Claim 1 of the '396 patent recites the following:

> 1. A method of treating a patient having a gout flare, the method consisting of:

orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then

orally administering 0.6 mg colchicine to the patient about one hour after administering the 1.2 mg colchicine,

the method providing an apparent total body clearance (C L/F) in a range of 2.4 L/hr to 5.3 L/hr.

ANSWER: Admitted.

180. Claim 6 of the ’396 patent recites the following:

6. A method of treating a patient having a gout flare, the method consisting of:

orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then

orally administering 0.6 mg colchicine to the patient about one hour after administering the 1.2 mg colchicine,

the method providing an apparent total volume of distribution (V_{area}/F) in a range of 0.77 L/hr to 1.7 L/hr.

ANSWER: Admitted.

181. Claim 11 of the ’396 patent recites the following:

11. A method of treating a patient having a gout flare, the method consisting of:

orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then

orally administering 0.6 mg colchicine to the patient about one hour after the first administration,

the method providing a maximum colchicine blood plasma concentration (C_{max}) in a range of 3.2 to 11.4 ng/mL, and a time after the first administration at which C_{max}, is reached (T_{max}) of 1.0 to 2.5 hr.

ANSWER: Admitted.

182. Claim 19 of the ’396 patent recites the following:

> 19. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration,
>
> the method providing a mean maximum colchicine blood plasma concentration (C_{max}) in a range of 3.8 to 8.6 ng/mL and a mean time after the first administration at which C_{max}, is reached (T_{max}) in a range of 1.4 to 2.2 hr.

ANSWER: Admitted.

183. Par’s ANDA Product is not especially adapted for infringement of the ’396 patent because Par’s ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

184. Physicians can and will prescribe Par’s ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient.

ANSWER: Admitted.

185. Par will not contribute to the infringement of any claim of the ’396 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

186. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par’s ANDA Product of the

’396 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

187. A judicial declaration that Par’s ANDA Product will not contribute to the infringement of the ’396 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XIII
(Non-Infringement of the ’721 Patent)

188. Par incorporates by reference Paragraphs 1 through 187 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 187 of its Reply to Par’s Counterclaims.

189. The ’721 patent has four claims.

ANSWER: Admitted.

190. Claim 1 of the ’721 patent is the only independent claim in the ’721 patent.

ANSWER: Admitted.

191. Claims 2-4 of the ’721 patent depend, either directly or indirectly, from claim 1.

ANSWER: Admitted.

192. Claim 1 of the ’721 patent recites the following:

> 1. A method of treating a patient in need of treatment for acute gout flares with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of amount of colchicine to the patient who is receiving concomitant administration of verapamil,
>
> wherein the adjusted daily dosage amount of colchicine is 50% to 75% of an intended daily dosage amount of colchicine,
>
> wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant verapamil, wherein the intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil is 1.2 mg at the first sign of flare, followed by 0.6 mg one hour later, and wherein the concomitantly administered dose of verapamil is 240 mg per day.

ANSWER: Admitted.

193. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of verapamil.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with verapamil. Takeda denies any remaining allegations in this paragraph.

194. Claim 1 of the '721 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes an "intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil," which "is 1.2 mg at the first sign of flare, followed by 0.6 mg one hour later[.]"

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

195. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares who is not receiving concomitant administration of verapamil.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with verapamil. Takeda denies any remaining allegations in this paragraph.

196. Par will not contribute to the infringement of any claim of the '721 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

197. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '721 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

198. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '721 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XIV
(Non-Infringement of the '722 Patent)

199. Par incorporates by reference Paragraphs 1 through 198 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 199 of its Reply to Par's Counterclaims.

200. The '722 patent has two claims.

ANSWER: Admitted.

201. Claim 1 of the '722 patent is the only independent claim in the '722 patent.

ANSWER: Admitted.

202. Claim 2 of the '722 patent depends from claim 1.

ANSWER: Admitted.

203. Claim 1 of the '722 patent recites the following:

> 1. A method of treating a patient in need of treatment for prophylaxis of gout flares with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of amount of colchicine to the patient who is receiving concomitant administration of verapamil,
>
> wherein the adjusted daily dosage amount of colchicine is 50% to 75% of an intended daily dosage amount of colchicine,
>
> wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant verapamil, wherein the intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil is 0.6 mg twice daily or 0.6 mg once daily, and wherein the concomitantly administered dose of verapamil is 240 mg per day.

ANSWER: Admitted.

204. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of verapamil.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with verapamil. Takeda denies any remaining allegations in this paragraph.

205. Claim 1 of the '722 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes an "intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil," which "is 0.6 mg twice daily or 0.6 mg once daily[.]"

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

206. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of verapamil.

ANSWER: This paragraph contains legal conclusions which Takeda believes no response is required. To the extent a response is required, Takeda admits that a physician could prescribe Par's ANDA product to a patient who is not otherwise also being treated with verapamil. Takeda denies any remaining allegations in this paragraph.

207. Par will not contribute to the infringement of any claim of the '722 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

208. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '722 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

209. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '722 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XV
(Non-Infringement of the '519 Patent)

210. Par incorporates by reference Paragraphs 1 through 209 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 209 of its Reply to Par's Counterclaims.

209. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '519 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

210. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '519 patent under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

211. [sic] A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the ’519 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

212. [sic] A judicial declaration that Par’s ANDA Product will not infringe the ’519 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XVI
(Non-Infringement of the ’731 Patent)

213. [sic] Par incorporates by reference Paragraphs 1 through 213 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 213 of its Reply to Par’s Counterclaims.

211. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical’s Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the ’731 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

212. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '731 patent under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

214. [sic] A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the '731 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

215. [sic] A judicial declaration that Par's ANDA Product will not infringe the '731 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XVII
(Non-Infringement of the '298 Patent)

216. [sic] Par incorporates by reference Paragraphs 1 through 215 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 215 of its Reply to Par's Counterclaims.

213. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '298 patent.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

214. [sic] The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '298 patent under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

217. [sic] A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

218. A judicial declaration that Par's ANDA Product will not infringe the '298 patent is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XIX
(Invalidity of the '758 Patent)

219. Par incorporates by reference Paragraphs 1 through 218 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 218 of its Reply to Par's Counterclaims.

220. The claims of the '758 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

221. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '758 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

222. A judicial declaration that the '758 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XX
(Invalidity of the '004 Patent)

223. Par incorporates by reference Paragraphs 1 through 222 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 222 of its Reply to Par's Counterclaims.

224. The claims of the '004 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

225. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '004 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph

226. A judicial declaration that the '004 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXI
(Invalidity of the '681 Patent)

227. Par incorporates by reference Paragraphs 1 through 226 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 226 of its Reply to Par's Counterclaims.

228. The claims of the ’681 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

229. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’681 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

230. A judicial declaration that the ’681 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXII
(Invalidity of the’269 Patent)

231. Par incorporates by reference Paragraphs 1 through 230 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 230 of its Reply to Par’s Counterclaims.

232. The claims of the ’269 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

233. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '269 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

234. A judicial declaration that the '269 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXIII
(Invalidity of the '647 Patent)

235. Par incorporates by reference Paragraphs 1 through 234 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 234 of its Reply to Par's Counterclaims.

236. The claims of the '647 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

237. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '647 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

238. A judicial declaration that the '647 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXIV
(Invalidity of the '938 Patent)

239. Par incorporates by reference Paragraphs 1 through 238 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 238 of its Reply to Par's Counterclaims.

240. The claims of the '938 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

241. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '938 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

242. A judicial declaration that the '938 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXV
(Invalidity of the '296 Patent)

243. Par incorporates by reference Paragraphs 1 through 242 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 242 of its Reply to Par's Counterclaims.

244. The claims of the '296 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

245. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '296 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but

denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

246. A judicial declaration that the ’296 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXVI
(Invalidity of the ’655 Patent)

247. Par incorporates by reference Paragraphs 1 through 246 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 246 of its Reply to Par’s Counterclaims.

248. The claims of the ’655 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

249. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’655 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

250. A judicial declaration that the ’655 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXVII
(Invalidity of the '395 Patent)

251. Par incorporates by reference Paragraphs 1 through 250 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 250 of its Reply to Par's Counterclaims.

252. The claims of the '395 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

253. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '395 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

254. A judicial declaration that the '395 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXVIII
(Invalidity of the '396 Patent)

255. Par incorporates by reference Paragraphs 1 through 254 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 254 of its Reply to Par's Counterclaims.

256. The claims of the '396 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

257. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '396 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

258. A judicial declaration that the '396 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXIX
(Invalidity of the '721 Patent)

259. Par incorporates by reference Paragraphs 1 through 258 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 258 of its Reply to Par's Counterclaims.

260. The claims of the '721 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

261. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '721 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

262. A judicial declaration that the '721 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXX
(Invalidity of the '722 Patent)

263. Par incorporates by reference Paragraphs 1 through 262 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 262 of its Reply to Par's Counterclaims.

264. The claims of the ’722 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

265. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’722 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

266. A judicial declaration that the ’722 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXI
(Invalidity of the ’519 Patent)

267. Par incorporates by reference Paragraphs 1 through 266 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 266 of its Reply to Par’s Counterclaims.

268. The claims of the ’519 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

269. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '519 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

270. A judicial declaration that the '519 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXII
(Invalidity of the '731 Patent)

271. Par incorporates by reference Paragraphs 1 through 270 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 270 of its Reply to Par's Counterclaims.

272. The claims of the '731 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

273. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’731 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

274. A judicial declaration that the ’731 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXIII
(Invalidity of the ’297 Patent)

275. Par incorporates by reference Paragraphs 1 through 274 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 274 of its Reply to Par’s Counterclaims.

276. The claims of the ’297 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

277. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’297 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

278. A judicial declaration that the '297 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXIV
(Invalidity of the '298 Patent)

279. Par incorporates by reference Paragraphs 1 through 278 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 279 of its Reply to Par's Counterclaims.

280. The claims of the '298 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

281. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par's infringement of the FMF Patents and the Gout Patents, but

denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

282. A judicial declaration that the ’298 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXV
(Invalidity of the ’648 Patent)

283. Par incorporates by reference Paragraphs 1 through 282 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 282 of its Reply to Par’s Counterclaims.

284. The claims of the ’648 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

285. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the ’648 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that there is an actual controversy concerning Par’s infringement of the FMF Patents and the Gout Patents, but denies that Par has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

286. A judicial declaration that the ’648 patent is invalid is warranted.

ANSWER: Denied.

COUNTERCLAIM COUNT XXXVI
(Exceptional Case)

287. Par incorporates by reference Paragraphs 1 through 286 of its Counterclaims as if fully set forth herein.

ANSWER: Takeda incorporates by reference its responses to paragraphs 1 through 286 of its Reply to Par's Counterclaims.

288. This is an exceptional case under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

289. Par should receive an award of its attorneys' fees, costs, and expenses in this action.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

PAR'S PRAYER FOR RELIEF

To the extent that this section may be deemed to allege any facts or any factual or legal entitlements to the relief requested, Takeda denies each and every such allegation. Specifically, Takeda denies that Par is entitled to any of the requested relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Counterclaim-Defendant Takeda respectfully requests this Court to enter judgment against Defendants/Counterclaim-Plaintiffs Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. as follows:

A. dismissing Defendants Par's counterclaims with prejudice;

B. finding that this is an exceptional case and granting Takeda reasonable attorney's fees pursuant to 35 U.S.C. § 285;

C. awarding Takeda the relief requested in its Complaint; and

D. awarding Takeda any further and additional relief as this Court deems just and proper.

Date: October 9, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on October 9, 2014, upon the following individuals via electronic mail:

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